

**New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplements  
Approved (CY 2008)**

**NDA Efficacy Supplements Approved (N, SE1-SE7)**

ESTABLISHED NAME	APPLICANT	APPLICATION NUMBER	SUPPLEMENT TYPE	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATIONS
TADALAFIL	ELI LILLY	021368	SE2	011		07-Dec-06	07-Jan-08	13	PROVIDES FOR THE TREATMENT OF ERECTILE DYSFUNCTION.
COLESEVELAM HYDROCHLORIDE	DAIICHI SANKYO	021176	SE1	017		22-Dec-06	18-Jan-08	12.9	PROVIDES AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GYLCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS.
MICAFUNGIN SODIUM	ASTELLAS	021506	SE1	008		22-Dec-06	22-Jan-08	13	PROVIDES FOR THE TREATMENT OF PATIENTS WITH CANDIDEMIA, ACUTE DISSEMINATED CANDIDIASIS, CANDIDA PERITONITIS AND ABSCESESSES.
EPLERENONE	PFIZER	021437	SE5	005		01-Aug-07	31-Jan-08	6	PROVIDES FOR THE TREATMENT OF HYPERTENSION IN PEDIATRIC PATIENTS.
LAMIVUDINE	GLAXOSMITHKLINE	020564	SE5	028	Y	03-Aug-07	01-Feb-08	6	PROVIDES FOR THE TREATMENT IN PEDIATRIC PATIENTS FOR WHOM A SOLID ORAL DOSAGE FORM IS APPROPRIATE.
MOMETASONE FUROATE	SCHERING	021067	SE5	003		02-Apr-07	01-Feb-08	10	PROVIDES FOR THE MAINTENANCE TREATMENT OF ASTHMA IN CHILDREN 4-11 YEARS OF AGE.
ARIPIPRAZOLE	OTSUKA	021436	SE5	021	Y	29-Aug-07	27-Feb-08	6	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
ARIPIPRAZOLE	OTSUKA	021713	SE5	016	Y	07-Sep-07	27-Feb-08	5.7	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
ARIPIPRAZOLE	OTSUKA	021729	SE5	008	Y	07-Sep-07	27-Feb-08	5.7	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
ARIPIPRAZOLE	OTSUKA	021866	SE5	008	Y	07-Sep-07	27-Feb-08	5.7	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
PALONOSETRON HYDROCHLORIDE	HELSINN	021372	SE1	008		04-May-07	29-Feb-08	9.9	PROVIDES FOR THE PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING FOR UP TO 24 HOURS FOLLOWING SURGERY.
OCTREOTIDE ACETATE	NOVARTIS	021008	SE1	021		28-Feb-07	03-Mar-08	12.1	PROVIDES FOR THE ADDITION OF NEW INFORMATION TO THE PACKAGE INSERT REGARDING THE TUMOR SHRINKAGE POTENTIAL ON GH-SECRETING PITUITARY ADENOMAS.
INSULIN ASPART RECOMBINANT	NOVO NORDISK	020986	SE5	047		14-May-07	14-Mar-08	10	PROVIDES FOR PEDIATRIC PUMP USE.

ZOLEDRONIC ACID	NOVARTIS	021223	SE5	016	Y	24-Sep-07	20-Mar-08	5.9	PROVIDES FOR THE PHARMACOKINETICS, EFFICACY AND SAFETY DATA IN PEDIATRIC PATIENTS WITH SEVERE OSTEOGENESIS IMPERFECTA IN RESPONSE TO FDA'S PEDIATRIC WRITTEN REQUEST.
DIVALPROEX SODIUM	ABBOTT	019680	SE5	024	Y	24-Sep-07	24-Mar-08	6	PROVIDES FOR USE AS MONOTHERAPY AND ADJUNCTIVE THERAPY OF COMPLEX PARTIAL SEIZURES AND SIMPLE AND COMPLEX ABSENCE SEIZURES; ADJUNCTIVE THERAPY IN PATIENTS WITH MULTIPLE SEIZURE TYPES THAT INCLUDE ABSENCE SEIZURES.
DIVALPROEX SODIUM	ABBOTT	021168	SE5	015	Y	24-Sep-07	24-Mar-08	6	PROVIDES FOR USE AS: (1) AN ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR DISORDER, WITH OR WITHOUT PSYCHOTIC FEATURES. (2) MONOTHERAPY AND ADJUNCTIVE THERAPY OF COMPLEX PARTIAL SEIZURES AND SIMPLE AND COMPLEX ABSENCE SEIZURES; ADJUNCTIVE THERAPY IN PATIENTS WITH MULTIPLE SEIZURE TYPES THAT INCLUDE ABSENCE SEIZURES. (3) PROPHYLAXIS OF MIGRAINE HEADACHES.
DIVALPROEX SODIUM	ABBOTT	022267	N	000	Y	24-Sep-07	24-Mar-08	6	PROVIDES FOR TREATMENT IN MANIA ASSOCIATED WITH BIPOLAR DISORDER IN CHILDREN AND ADOLESCENTS.
ATAZANAVIR SULFATE	BRISTOL MYERS SQUIBB	021567	SE5	015	Y	26-Sep-07	25-Mar-08	6	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS (AGES 6 TO 18 YEARS OF AGE).
ALOSETRON HYDROCHLORIDE	PROMETHEUS	021107	SE2	013		01-Jun-07	01-Apr-08	10	PROVIDES FOR THE ADDITION OF ITEMS TO THE PACKAGE INSERT (1) CHANGES TO THE DOSING REGIMEN FOR PATIENTS WHO BECOME CONSTIPATED WHILE USING LOTRONEX. (2) THE ADDITION OF CLINICAL STUDY INFORMATION FOR 0.5 MG ONCE DAILY DOSING. (3) THE ADDITION OF CLINICAL PHARMACOLOGY INFORMATION FOR THE METABOLISM OF LOTRONEX. (4) THE ADDITION OF DRUG INTERACTION INFORMATION. (5) THE PACKAGE INSERT HAS BEEN REFORMATTED TO MEET THE PHYSICIAN'S LABELING RULE FORMAT.
FLUVOXAMINE MALEATE	JAZZ	22235	N	000		21-Jun-07	14-Apr-08	9.8	PROVIDES FOR MAINTENANCE TREATMENT OF OBSESSIVE COMPULSIVE DISORDER (OCD)
RISEDRONATE SODIUM	PROCTER GAMBLE	020835	SE2	030		22-Jun-07	22-Apr-08	10	PROVIDES FOR THE USE (150 MG TABLETS) AS A ONCE DAILY DOSE TO TREAT POSTMENOPAUSAL OSTEOPOROSIS (PMO).
LISDEXAMFETAMINE DIMESYLATE	SHIRE DEVELOPMENT	021977	SE5	001		29-Jun-07	23-Apr-08	9.8	PROVIDES FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER IN THE ADULT POPULATION.
LUBIPROSTONE	SUCAMPO	021908	SE1	005		29-Jun-07	29-Apr-08	10	PROVIDES FOR THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN WOMEN ≥ 18 YEARS OLD.
FLUTICASONE PROPIONATE AND SALMETEROL XINAFOATE	GLAXOSMITHKLINE	021077	SE2	029		10-Oct-06	30-Apr-08	18.7	PROVIDES FOR THE MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION AND REDUCING EXACERBATIONS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCH.

TECHNETIUM TC-99M SESTAMIBI	LANTHEUS MEDICAL IMAGING	019785	SE5	018		29-Oct-07	30-Apr-08	6	PROVIDES FOR PEDIATRIC STUDY REPORTS SUBMITTED IN RESPONSE TO THE AGENCY'S WRITTEN REQUEST TO QUALIFY THIS PRODUCT FOR PEDIATRIC EXCLUSIVITY.
LEVOFLOXACIN	ORTHO-MCNEIL-JANSSEN	020634	SE5	047		05-Jul-07	05-May-08	10	PROVIDES FOR INHALATIONAL ANTHRAX (POST-EXPOSURE) TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)(TABLETS).
LEVOFLOXACIN	ORTHO-MCNEIL-JANSSEN	020635	SE5	051		05-Jul-07	05-May-08	10	PROVIDES FOR INHALATIONAL ANTHRAX (POST-EXPOSURE) TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)(INJECTION).
LEVOFLOXACIN	ORTHO-MCNEIL-JANSSEN	021721	SE5	015		05-Jul-07	05-May-08	10	PROVIDES FOR INHALATIONAL ANTHRAX (POST-EXPOSURE) TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)(ORAL SOLUTION).
ARIPIPRAZOLE	OTSUKA	021436	SE1	020	Y	11-Jul-07	06-May-08	9.9	PROVIDES FOR THE USE AS ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15 MG/DAY.
ARIPIPRAZOLE	OTSUKA	021436	SE2	019		11-Jul-07	06-May-08	9.9	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021713	SE1	015	Y	29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS AN ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021713	SE2	014		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021729	SE1	007		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS AN ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021729	SE2	006	Y	29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021866	SE1	007		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS AN ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.

ARIPIPRAZOLE	OTSUKA	021866	SE2	006		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ATOMOXETIN HYDROCHLORIDE	ELI LILLY	021411	SE1	005		16-Mar-04	07-May-08	49.7	PROVIDES FOR THE MAINTENANCE TREATMENT OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD) IN CHILDREN AND ADOLESCENTS.
QUETIAPINE FUMARATE	ASTRAZENECA	020639	SE1	037		19-Jul-07	13-May-08	9.8	PROVIDES FOR THE USE AS MAINTENANCE TREATMENT FOR BIPOLAR I DISORDER, AS ADJUNCTIVE THERAPY TO LITHIUM OR DIVALPROEX.
LEVETIRACETAM	UCB	021872	SE1	005		16-Jul-07	16-May-08	10	PROVIDES FOR THE USE AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES IN ADULTS AND CHILDREN 16 YEARS OF AGE AND OLDER WITH IDIOPATHIC GENERALIZED EPILEPSY.
ZOLEDRONIC ACID	NOVARTIS	021817	SE1	001		03-Aug-07	03-Jun-08	10	PROVIDES FOR THE INCLUSION OF INFORMATION UNDER CLINICAL STUDIES ON THE EFFICACY AND SAFETY TO RECLAST IN PATIENTS WITH A RECENT LOW-TRAUMA HIP FRACTURE.
EZETIMIBE	SCHERING	021445	SE5	020	Y	17-Dec-07	05-Jun-08	5.6	PROVIDES FOR THE RESULTS OF A PEDIATRIC STUDY IN ADOLESCENT BOYS AND POSTMENARCHAL GIRLS, AGES 10 TO 17 YEARS OF AGE, WITH HETEROZYGOUS FAMILIAL HYPERCHLOESTEROLEMIA.
DOXORUBICIN HYDROCHLORIDE LIPOSOME	ALZA	050718	SE7	033		10-Aug-07	10-Jun-08	10	PROVIDES FOR THE TREATMENT OF AIDS-RELATED KAPOSIS' SARCOMA AFTER FAILURE OF PRIOR SYSTEMIC CHEMOTHERAPY OR INTOLERANCE TO SUCH THERAPY.
SOMATROPIN	PFIZER	020280	SE1	060		02-Jul-07	12-Jun-08	11.4	PROVIDES FOR THE TREATMENT OF IDIOPATHIC SHORT STATURE IN PEDIATRIC PATIENTS WHOSE EPIPHYSES ARE NOT CLOSED AND FOR WHOM DIAGNOSTIC EVALUATION EXCLUDES OTHER CAUSES ASSOCIATED WITH SHORT STATURE THAT SHOULD BE OBSERVED OR TREATED BY OTHER MEANS.
EZETIMIBE/SIMVASTATIN	MERCK & CO	021687	SE5	023	Y	19-Dec-07	13-Jun-08	5.8	PROVIDES THE RESULTS OF A PEDIATRIC STUDY OF THE USE IN ADOLESCENT BOYS AND POSTMENARCHAL GIRLS, AGES 10 TO 17 YEARS OF AGE, WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.
DULOXETINE HYDROCHLORIDE	ELI LILLY	022148	N	000		14-Aug-07	13-Jun-08	10	PROVIDES FOR THE MANAGEMENT OF FIBROMYALGIA.
DUTASTERIDE	GLAXOSMITHKLINE	021319	SE1	014		21-Aug-07	19-Jun-08	10	PROVIDES FOR THE USE IN COMBINATION WITH TAMSULOSIN FOR THE TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA (BPH).
LOPINAVIR/RITONAVIR	ABBOTT	021251	SE5	022	Y	21-Dec-07	20-Jun-08	6	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 14 DAYS TO 6 MONTHS OF AGE AND FROM 12 TO 18 YEARS OF AGE.
BORTEZOMIB	MILLENNIUM	021602	SE1	015	Y	20-Dec-07	20-Jun-08	6	PROVIDES FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA.

TIPRANAVIR	BOEHRINGER INGELHEIM	021814	SE1	005	Y	21-Dec-07	23-Jun-08	6.1	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTED PEDIATRIC (AGE 2 TO 18 YEARS) PATIENTS WHO ARE TREATMENT-EXPERIENCED AND INFECTED WITH HIV-1 STRAINS RESISTANT TO MORE THAN ONE PROTEASE INHIBITOR.
NEVIRAPINE	BOEHRINGER INGELHEIM	020636	SE5	027	Y	20-Dec-07	24-Jun-08	6.1	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 15 DAYS AND OLDER AND FOR PATIENTS WITH HEPATIC IMPAIRMENT.
NEVIRAPINE	BOEHRINGER INGELHEIM	020933	SE5	017	Y	20-Dec-07	24-Jun-08	6.1	PROVIDES FOR THE TREATMENT OF NEONATES AND INFANTS < 2 MONTHS OF AGE, PEDIATRIC PATIENTS > 2 MONTHS OF AGE, AND FOR PATIENTS WITH HEPATIC IMPAIRMENT.
METHYLPHENIDATE HYDROCHLORIDE	ORTHO-MCNEIL-JANSSEN	021121	SE5	017		29-Aug-07	27-Jun-08	10	PROVIDES FOR THE USE OF TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS (18 AND OLDER).
RABEPRAZOLE SODIUM	EISAI MEDICAL	020973	SE5	022		31-Dec-07	30-Jun-08	6	PROVIDES FOR SHORT-TERM TREATMENT SYMPTOMATIC GERD IN ADOLESCENT PATIENTS 12 YEARS OF AGE AND ABOVE.
AMLODIPINE BESYLATE/VALSARTAN	NOVARTIS	021990	SE1	003		24-Sep-07	23-Jul-08	10	PROVIDES FOR THE INITIAL THERAPY IN PATIENTS LIKELY TO NEED MULTIPLE DRUGS TO ACHIEVE THEIR BLOOD PRESSURE GOALS.
CASPOFUNGIN ACETATE	MERCK	021227	SE5	021	Y	31-Jan-08	29-Jul-08	5.9	PROVIDES FOR THE TREATMENT OF EMPIRICAL THERAPY, CANDIDEMIA (CANDIDA INFECTIONS), ESOPHAGEAL CANDIDIASIS, AND FOR INVASIVE ASPERGILLOSIS.
VALSARTAN	NOVARTIS	020818	SE1	036		14-Dec-06	31-Jul-08	19.6	PROVIDES FOR THE USE AS INITIAL THERAPY IN PATIENTS WHO ARE LIKELY TO NEED MULTIPLE DRUGS TO ACHIEVE THEIR BLOOD PRESSURE GOALS.
TENOFOVIR DISOPROXIL FUMARATE	GILEAD	021356	SE1	025		11-Oct-07	11-Aug-08	10	PROVIDES FOR TREATMENT OF CHRONIC HEPATITIS B.
ROCURONIUM BROMIDE	ORGANON USA	020214	SE5	030	Y	11-Jan-08	28-Aug-08	7.6	PROVIDES FOR USE IN PEDIATRIC PATIENTS.
VALACYCLOVIR HCL	GLAXOSMITHKLINE	020487	SE5	014	Y	10-Dec-07	02-Sep-08	8.8	PROVIDES FOR THE TREATMENT OF HERPES ZOSTER
ALBUTEROL SULFATE	TEVA GLOBAL	021457	SE5	013		16-Nov-07	16-Sep-08	10	PROVIDES FOR THE TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE/ FOR THE PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM
ZIDOVUDINE	GLAXOSMITHKLINE	019655	SE2	046		17-Sep-08	19-Sep-08	0.1	PROVIDES FOR THE TREATMENT OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND AIDS-RELATED COMPLEX (ARC).
ZIDOVUDINE	GLAXOSMITHKLINE	19910	SE2	033	Y	21-Mar-08	19-Sep-08	6	PROVIDES FOR THE MANAGEMENT OF CERTAIN ADULT PATIENTS WITH SYMPTOMATIC HIV INFECTION
TRIAMCINOLONE ACETONIDE	SANOFI AVENTIS	020468	SE5	024		19-Nov-07	19-Sep-08	10	PROVIDES FOR THE TREATMENT OF SEASONAL AND PERENNIAL RHINITIS SYMPTOMS
ZIDOVUDINE	GLAXOSMITHKLINE	020518	SE2	016		17-Sep-08	19-Sep-08	0.1	PROVIDES FOR THE TREATMENT OF HIV INFECTION
ERLOTINIB HCL	OSI	021743	SE2	011		21-Nov-07	19-Sep-08	10	PROVIDES FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER AFTER FAILURE OF AT LEAST ONE PRIOR CHEMOTHERAPY REGIMEN AND STUDY OF SKIN
PEMETREXED DISODIUM	LILLY	021462	SE1	015		28-Aug-07	26-Sep-08	13	PROVIDES FOR THE TREATMENT OF MALIGNANT PLEURAL MESOTHELIOMA

IMATINIB MESYLATE TABLETS	NOVARTIS	021588	SE7	024		29-Nov-07	26-Sep-08	9.9	PROVIDES FOR THE TREATMENT OF PHILADELPHIA POSITIVE CHRONIC MYELOID LEUKEMIA
DIDANOSINE	BRISTOL MYERS SQUIBB	021183	SE5	020	Y	01-Apr-08	29-Sep-08	6	PROVIDES FOR THE TREATMENT OF ADULT PATIENTS WITH HIV
ATAZANAVIR SULFATE	BRISTOL MYERS SQUIBB	021567	SE5	017		21-Dec-07	30-Sep-08	9.3	PROVIDES FOR AN ALTERNATIVE DOSING REGIMEN CO-ADMINISTERED WITH RITONAVIR FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT NAIVE PATIENTS
AZITHROMYCIN EXTENDED RELEASE FOR ORAL S	PFIZER GLOBAL	050797	SE5	008		22-Oct-07	07-Oct-08	11.5	PROVIDES FOR THE TREATMENT OF COMMUNITY ACQUIRED PNEUMONIA, ACUTE BACTERIAL SINUSITIS
QUETIAPINE FUMARATE	ASTRAZENECA	022047	SE1	006		19-Dec-07	08-Oct-08	9.7	PROVIDES FOR THE TREATMENT OF SCHIZOPHRENIA
QUETIAPINE FUMARATE	ASTRAZENECA	022047	SE1	007		19-Dec-07	08-Oct-08	9.7	PROVIDES FOR THE TREATMENT OF SCHIZOPHRENIA
QUETIAPINE FUMARATE	ASTRAZENECA	022047	SE1	008		19-Dec-07	08-Oct-08	9.7	PROVIDES FOR THE TREATMENT OF SCHIZOPHRENIA
ZOLMITRIPTAN NASAL SPRAY 0.5/2.5/5 MG	ASTRAZENECA	021450	SE5	005		14-Dec-07	14-Oct-08	10	PROVIDES FOR THE ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN ADULTS
DEXMEDETOMIDINE	HOSPIRA	021038	SE1	010		19-Dec-07	17-Oct-08	10	PROVIDES FOR SEDATION OF INITIALLY INTUBATED AND MECHANICALLY VENTILATED PATIENTS IN AN ICU
DARUNAVIR	TIBOTEC	021976	SE5	007		21-Dec-07	21-Oct-08	10	PROVIDES FOR THE TREATMENT OF HIV INFECTION
DARUNAVIR	TIBOTEC	021976	SE7	006		21-Dec-07	21-Oct-08	10	PROVIDES FOR THE TREATMENT OF HIV INFECTION
INSULIN GLULISINE	SANOFI AVENTIS	021629	SE5	015		28-Jun-07	24-Oct-08	15.9	PROVIDES FOR THE TREATMENT OF DIABETES MELLITUS
LANSOPRAZOLE	TAKEDA	020406	SE5	067	Y	28-Apr-08	28-Oct-08	6	PROVIDES FOR THE TREATMENT OF REFLUX ESOPHAGITIS/REFLUX ESOPHAGITIS: MAINTENANCE
LANSOPRAZOLE	TAKEDA	021281	SE5	024	Y	28-Apr-08	28-Oct-08	6	PROVIDES FOR THE SHORT TERM TREATMENT FOR HEALING/SYMPPTOM RELIEF OF ESOPHAGITIS EROSIVE
LANSOPRAZOLE	TAKEDA	021428	SE5	017	Y	28-Apr-08	28-Oct-08	6	PROVIDES FOR THE TREATMENT FOR GASTROESOPHAGEAL REFLUX
FESOTERODINE FUMARATE	PFIZER	022303	N	000		31-Dec-07	31-Oct-08	10.0	PROVIDES FOR THE TREATMENT OF PATIENTS WITH INDOLENT B-CELL NON-HODGKIN'S LYMPHOMA (NHL)
SOMATROPIN	NOVO NORDISK	021148	SE1	023		20-Sep-07	31-Oct-08	13.4	PROVIDES FOR TREATMENT OF GROWTH FAILURE IN CHILDREN BORN SMALL FOR GESTATIONAL AGE (SGA) WITH NO CATCH-UP BY AGE 2-4 YEARS.
RANOLAZINE	CV	021526	SE1	004	Y	27-Sep-07	05-Nov-08	13.3	PROVIDES FOR THE TREATMENT OF CHRONIC ANGINA
ROSUVASTATIN CALCIUM	ASTRAZENECA	021366	SE1	013	Y	10-Jan-08	06-Nov-08	9.9	PATIENTS WITH PRIMARY DYSBETALIPOPROTEINEMIA (FREDRICKSON TYPE III)
ESTROGENS CONJUGATED	WYETH	020216	SE1	060	Y	25-Sep-07	07-Nov-08	13.4	PROVIDES FOR THE TREATMENT OF MODERATE TO SEVERE DYSPAREUNIA DUE TO MENOPAUSE AND A NEW DOSAGE REGIMEN OF TWICE WEEKLY
MARAVIROC	PFIZER	022128	SE7	001	Y	31-Jan-08	25-Nov-08	9.8	TREATMENT OF PATIENTS WITH CCR5-TROPIC HIV-1
IBANDRONATE SODIUM	ROCHE	021455	SE1	007	Y	28-Jan-08	28-Nov-08	10	PROVIDES FOR THE TREATMENT AND PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

ARIMIDEX	ASTRAZENECA	022214	N	000	Y	05-Sep-07	05-Dec-08	15	PROVIDES FOR THE ADDITION OF SAFETY, EFFICACY, AND PHARMACOKINETIC INFORMATION IN THE PEDIATRIC POPULATION, SPECIFICALLY MALE PUBERTAL PATIENTS WITH GYNecomastia AND FEMALE PEDIATRIC PATIENTS WITH MCCUNE-ALBRIGHT SYNDROME WITH PROGRESSIVE PRECOCIOUS PUBERTY, TO THE PEDIATRIC USE SECTION OF THE LABELING.
PREZISTA	TIBOTEC	021976	SE5	009	Y	20-Jun-08	18-Dec-08	6	PROVIDES DOSING RECOMMENDATIONS FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV-1) INFECTED PEDIATRIC PATIENTS 6 TO LESS THAN 18 YEARS OF AGE AND TO INCLUDE TWO NEW DOSAGE STRENGTHS, 75MG AND 150 MG TABLETS.
ZIAGEN	GLAXOSMITHKLINE	020977	SE2	019	Y	20-Jun-08	19-Dec-08	6	PROVIDES FOR TWICE DAILY DOSING FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS WEIGHING GREATER THAN OR EQUAL TO 14 KG.
GLEEVEC	NOVARTIS	021588	SE1	025	Y	24-Jun-08	19-Dec-08	5.9	PROVIDES FOR THE ADJUVANT TREATMENT OF ADULT PATIENTS FOLLOWING COMPLETE GROSS RESECTION OF KIT (CD117) POSITIVE GASTROINTESTINAL STROMAL TUMORS (GIST).
RECLAST	NOVARTIS	021817	SE1	002		15-Feb-08	19-Dec-08	10.1	PROVIDES FOR TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS.
CASODEX	ASTRAZENECA	022310	N	000	Y	25-Jun-08	19-Dec-08	5.8	PROVIDES FOR THE ADDITION OF SAFETY, EFFICACY, AND PHARMACOKINETIC INFORMATION IN THE PEDIATRIC POPULATION, SPECIFICALLY BOYS WITH FAMILIAL MALE-LIMITED PRECOCIOUS PUBERTY (TESTOTOXICOSIS), TO THE PEDIATRIC USE SECTION OF THE LABELING.
LATISSE	ALLERGAN	022369	N	000	Y	27-Jun-08	24-Dec-08	5.9	PROVIDES FOR TREATMENT OF HYPOTRICHOSIS OF THE EYELASHES BY INCREASING THEIR GROWTH INCLUDING LENGTH, THICKNESS, AND DARKNESS.
CELECOXIB	GD SEARLE	020998	SE2	027		29-Feb-08	31-Dec-08	10.1	PROVIDES FOR CHANGES TO THE FOLLOWING SECTIONS OF THE PACKAGE INSERT: DOSAGE AND ADMINISTRATION- SPECIAL POPULATIONS, WARNING AND PRECAUTIONS- CARDIOVASCULAR EFFECTS, DRUG INTERACTIONS, USE IN SPECIFIC POPULATIONS- NURSING MOTHERS AND POOR METABOLIZERS OF CYP2C9 SUBSTRATES, CLINICAL PHARMACOLOGY- PHARMACOKINETICS, METABOLISM, AND CLINICAL STUDIES- SPECIAL STUDIES.

**NDA Efficacy Supplements Approved (SE8)**

ESTABLISHED NAME	APPLICANT	APPLICATION TYPE	APPLICATION NUMBER	SUPPLEMENT TYPE	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)
SIROLIMUS	WYETH	N	021083	SE8	033		14-Dec-06	14-Jan-08	13
SIROLIMUS	WYETH	N	021110	SE8	043		14-Dec-06	14-Jan-08	13
SITAGLIPTIN METFORMIN HYDROCHLORIDE	MERCK	N	022044	SE8	003		27-Apr-07	26-Feb-08	10
SITAGLIPTIN METFORMIN HYDROCHLORIDE	MERCK	N	022044	SE8	004		11-May-07	26-Feb-08	9.6

PALONOSETRON HYDROCHLORIDE	HELSINN	N	021372	SE8	010		04-May-07	29-Feb-08	9.9
DAPSONE	QLT USA	N	021794	SE8	005		23-May-07	14-Mar-08	9.7
ALBUTEROL SULFATE	GLAXOSMITHKLINE	N	020983	SE8	016	Y	28-Sep-07	26-Mar-08	5.9
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	MCNEIL CONSUMER HEALTHCARE	N	020606	SE8	014		29-Dec-06	30-Apr-08	16
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	MCNEIL CONSUMER HEALTHCARE	N	021140	SE8	011		29-Dec-06	30-Apr-08	16
ARGATROBAN	ENCYSIVE	N	020883	SE8	014	Y	29-Jun-05	05-May-08	34.2
TENOFOVIR DISOPROXIL FUMARATE	GILEAD	N	021356	SE8	024		17-Jul-07	16-May-08	10
EMTRICITABINE	GILEAD	N	021500	SE8	011		17-Jul-07	16-May-08	10
EMTRICITABINE/TENOFOVIR DISOPROXIL	GILEAD	N	021752	SE8	016		17-Jul-07	16-May-08	10
EMTRICITABINE	GILEAD	N	021896	SE8	005		18-Jul-07	16-May-08	10
OXALIPLATIN	SANOFI-AVENTIS	N	021492	SE8	010		21-Nov-07	21-May-08	6
EFAVIREN/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	GILEAD	N	021937	SE8	009		17-Jul-07	06-Jun-08	10.7
METHYL AMINOLEVULINATE HYDROCHLORIDE	CATO	N	021415	SE8	003		28-Jun-07	26-Jun-08	12
VERTEPORFIN	QLT	N	021119	SE8	013		08-Jul-04	30-Jun-08	47.8
ROSIGLITAZONE MALEATE	GLAXOSMITHKLINE	N	021071	SE8	026		28-Feb-07	10-Jul-08	16.4
ABACAVIR SULFATE	GLAXOSMITHKLINE	N	020977	SE8	017		20-Sep-07	18-Jul-08	9.9
ABACAVIR SULFATE	GLAXOSMITHKLINE	N	020978	SE8	020		20-Sep-07	18-Jul-08	9.9
ATOMOXETINE HYDROCHLORIDE	ELI LILLY	N	021411	SE8	024		27-Sep-07	23-Jul-08	9.9
ENTECAVIR	BRISTOL-MYERS SQUIBB	N	021797	SE8	005		27-Sep-07	25-Jul-08	9.9
ENTECAVIR	BRISTOL-MYERS SQUIBB	N	021798	SE8	006		27-Sep-07	25-Jul-08	9.9
FLUOCINOLONE ACETONIDE	BAUSCH AND LOMB	N	021737	SE8	010		05-Oct-07	05-Aug-08	10
AZACITIDINE	PHARMION	N	050794	SE8	011	Y	29-Feb-08	20-Aug-08	5.7
PHOTOFRIN	AXCAN SCANDI	N	020451	SE8	019		10-Aug-07	08-Sep-08	13
CLOFARABINE	GENZYME	N	021673	SE8	005		19-Dec-07	17-Oct-08	10
DEXMETHYLPHENIDATE ER CAPSULES	NOVARTIS PHARMS	N	021802	SE8	012		21-Dec-07	17-Oct-08	9.9
RAMELTEON	TAKEDA GLOBAL	N	021782	SE8	008		20-Dec-07	20-Oct-08	10
RAMELTEON	TAKEDA GLOBAL	N	021782	SE8	009		20-Dec-07	20-Oct-08	10
RAMELTEON	TAKEDA GLOBAL	N	021782	SE8	010		20-Dec-07	20-Oct-08	10

**BLA Efficacy Supplements Approved**

PROPER NAME	APPLICANT	BLA NUMBER	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATION
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SE4	COMPARATIVE EFFICACY CLAIM
SE5	PATIENT POPULATION ALTERED
SE6	CHANGE THE MARKETING STATUS FROM PRESCRIPTION TO OVER-THE-COUNTER USE
SE7	COMPLETE THE TRADITIONAL APPROVAL OF A PRODUCT ORIGINALLY APPROVED UNDER SUBPART H (ACCELERATED APPROVAL)
SE8	INCORPORATE OTHER INFORMATION BASED ON AT LEAST ONE ADEQUATE AND WELL-CONTROLLED CLINICAL STUDY

Updated through 12/31/08